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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/238,405    05/05/94    CAPON

D    CELL5.3

EXAMINER

HM22/0526

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ART UNIT

PAPER NUMBER

1645

DATE MAILED:

05/26/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/238,405**

Applicant(s)  
**Capon et al**

Examiner  
**Robert C. Hayes**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on Mar 8, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 57, 59, 64, 65, 67, 69, and 71 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 57, 64, 65, 67, 69, and 71 is/are rejected.

☒ Claim(s) 59 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 03/08/99 has been entered.
2. The rejection of claim 65 under 35 U.S.C. 112, first paragraph is withdrawn due to Applicants' arguments, as they relate to the teachings of US Patent 4,965,204.
3. The rejection of claim 64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out which "protein" is being claimed, is withdrawn due to the amendment of the claim.
4. Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Applicants' arguments filed 03/08/99 as paper # 29 have been fully considered but they are not deemed to be persuasive.

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7. Claims 64-65, 67, 69 & 71 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,359,046, for the reasons made of record.

8. Claim 69 is again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons made of record, and as follows.

Applicants argue on pages 2-3 of the response that “the specification teaches at page 22 manipulating the cells to prevent expression of one or both class I and II antigens so that those cells are ‘invisible’ to the host”. In contrast to Applicants’ arguments, the claims are not directed to gene therapy methods, nor was such elected as part of the instant invention. In other words, Applicants’ arguments support the enablement rejection made of record, in that cells encompassed by the instant invention intrinsically contain Class I Major Histocompatibility Complex antigens, as previously made of record. Thus, arguments directed toward one “blocking expression...” are moot.

9. Claim 69 (as Applicants correctly point out this typographical error) is again rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it remains unclear what the metes and bounds for “substantially free” entail, and because it remains ambiguous how

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mammalian cells can be free of MHC antigens when they intrinsically contain these antigens.

Applicants' arguments are not persuasive, for the reasons addressed in the preceding paragraph, and because claims directed to gene therapy are not claimed, and would constitute a non-elected invention.

10. Claims 57, 64, 67, 69 & 71 are again rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al., for the reasons made of record, and as follows.

Applicants argue on pages 5-7 of the response that "[t]he instant claims recite that the cytoplasmic domain is one which initiates a signal", and therefore, "[t]he instant invention is distinguishable...". However, as previously made of record, Gross et al teach all structural limitations currently recited in the claims, in which induction of T-cell proliferation, interleukin production and target cell lysis occur; thereby, demonstrating that "initiation of a signal" has occurred, as claimed. In that no claim limitations are recited that structurally require the  $\zeta$  chain as the intracellular domain, Applicants' arguments are not persuasive, for the reasons made of record.

11. Claims 57, 64, 67, 69 & 71 are again rejected under 35 U.S.C. 102(b) as being anticipated by Kuwana et al., for the reasons made of record, and as follows.

As previously made of record, Kuwana et al. teach all structural limitations currently recited in the claims, in which cytoplasmic calcium concentrations are induced; thereby,

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demonstrating that "initiation of a signal" has occurred, as claimed. In that no claim limitations are recited that structurally require the  $\zeta$  chain as the intracellular domain, Applicants' arguments are not persuasive, for the reasons made of record.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCN

Robert C. Hayes, Ph.D.  
May 19, 1999

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